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Francis J. Tinney  
Patent Department  
Warner-Lambert Company  
2800 Plymouth Road  
Ann Arbor, Michigan 48105

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,376,858

CORRECTED  
NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,376,858, which claims the human drug product Neutrexin™, is eligible for patent term extension under 35 U.S.C. § 156. U.S. Patent No. 4,376,858 issued March 15, 1983 from an application that claimed priority under 35 U.S.C. § 120 to an application filed on October 31, 1980. Accordingly, the original expiration date of the patent is October 31, 2000. 35 U.S.C. § 154 The period of extension has been determined to be 1,286 days.

In response to a letter dated September 27, 1996 from Stuart Nightingale, M.D., Associate Commissioner for Health Affairs of the Food and Drug Administration, the period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 15, 1996. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,931) + 320 \\ &= 1,286 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The limitations of 35 U.S.C. 156(c)(3) and 156(g)(6) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,286 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 4,376,858

Granted: March 15, 1983

Original Expiration Date: October 31, 2000

Applicant: Norman L. Colbry

Owner of Record: Warner Lambert Company

Title: 2-4 DIAMINO-5-METHYL-6-[(3,4,5-  
TRIMETHOXYANILINO)  
METHYL]QUINAZOLINE SALTS

Classification: 544/291

Product Trade Name: Neutrexin™

Term Extended: 1,286 days

Extended Expiration Date: May 9, 2004

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: Neutrexin™

FDA Docket No.: 94E-0099